

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

**MILTON RAINBOLT, PAMELA MYERS,)
STEVE STROBEL, EVA HOWEY,)
GENEVA HOWARD, JULIE MELTON,)
HARRY WEIR, SHANDRA PEACE, and)
JULIE MALIK for decedent ANITA)
McPETERS,)**

Plaintiffs,)

vs.)

**PFIZER INC., PHARMACIA)
CORPORATION, and G.D. SEARLE LLC,)**

Defendants.)

Case No. 4:07-cv-0668-ERW

JURY TRIAL DEMANDED

**DEFENDANTS PFIZER INC., PHARMACIA CORPORATION, AND G.D. SEARLE
LLC'S ANSWER TO PLAINTIFFS' COMPLAINT**

Defendants Pfizer Inc., ("Pfizer"), Pharmacia Corporation, and G.D. Searle LLC ("Searle") (collectively referred to herein as "the Answering Defendants"), for their Answer to plaintiffs' Complaint ("plaintiffs' Complaint"), state as follows:

1. The Answering Defendants admit that plaintiffs brought this civil action seeking monetary damages, but deny that plaintiff is entitled to any relief or damages. The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 of plaintiffs' Complaint regarding plaintiff's alleged use of Bextra® and therefore deny the same. The Answering Defendants deny the remaining allegations of paragraph 1 of plaintiffs' Complaint.

2. The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 regarding plaintiff's

alleged use of Bextra® and citizenship and therefore deny the same. The Answering Defendants deny all remaining allegations in paragraph 2 of plaintiffs' Complaint.

3. The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 regarding plaintiff's alleged use of Bextra® and citizenship and therefore deny the same. The Answering Defendants deny all remaining allegations in paragraph 3 of plaintiffs' Complaint.

4. The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 regarding plaintiff's alleged use of Bextra® and citizenship and therefore deny the same. The Answering Defendants deny all remaining allegations in paragraph 4 of plaintiffs' Complaint.

5. The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 regarding plaintiff's alleged use of Bextra® and citizenship and therefore deny the same. The Answering Defendants deny all remaining allegations in paragraph 5 of plaintiffs' Complaint.

6. The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 6 regarding plaintiff's alleged use of Bextra® and citizenship and therefore deny the same. The Answering Defendants deny all remaining allegations in paragraph 6 of plaintiffs' Complaint.

7. The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 7 regarding plaintiff's alleged use of Bextra® and citizenship and therefore deny the same. The Answering Defendants deny all remaining allegations in paragraph 7 of plaintiffs' Complaint.

8. The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 8 regarding plaintiff's alleged use of Bextra® and citizenship and therefore deny the same. The Answering Defendants deny all remaining allegations in paragraph 8 of plaintiffs' Complaint.

9. The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 9 regarding plaintiff's alleged use of Bextra® and citizenship and therefore deny the same. The Answering Defendants deny all remaining allegations in paragraph 9 of plaintiffs' Complaint.

10. The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 10 regarding plaintiff's relationship to decedent, and decedent's use of Bextra® and citizenship, and therefore deny the same. The Answering Defendants deny all remaining allegations in paragraph 10 of plaintiffs' Complaint.

JURISDICTION AND VENUE

11. The Answering Defendants admit that this Court has jurisdiction because based on diversity and because the amount in controversy exceeds \$75,000 for each plaintiff's claim, but Answering Defendants deny that plaintiffs are entitled to any relief.

12. The Answering Defendants state that the allegations in paragraph 12 of plaintiffs' Complaint are legal conclusions to which no response is required. To the extent a response is required, the Answering Defendants deny the allegations in paragraph 12 of plaintiffs' Complaint.

PARTIES BEXTRA

13. The Answering Defendants admit that Pfizer is a Delaware corporation and that it is registered to do business in Missouri. The Answering Defendants admit that Pfizer has marketed Bextra® as a prescription drug for the indications set forth in the approved package insert and as permitted by law. The Answering Defendants deny all remaining allegations in paragraph 13 of plaintiffs' Complaint.

14. The Answering Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois that is registered to do business in Missouri. The Answering Defendants admit that, during certain periods of time, Bextra® was manufactured for Searle and the during certain periods of time, Searle marketed and distributed Bextra®. The Answering Defendants deny all remaining allegations in paragraph 14 of plaintiffs' Complaint.

15. The Answering Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. The Answering Defendants admit that, during certain periods of time, Pharmacia marketed Bextra®. The Answering Defendants deny all remaining allegations in paragraph 15 of plaintiffs' Complaint.

16. The Answering Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. The Answering Defendants further admit that Pfizer has marketed Bextra® as a prescription drug for the indications set forth in the approved package insert and as permitted by law. The Answering Defendants further admit that, during certain periods of time, Bextra® was manufactured for Searle and the during certain periods of time, Searle marketed and distributed Bextra®. The Answering Defendants further admit that, during certain periods of time,

Pharmacia marketed Bextra®. The Answering Defendants deny all remaining allegations in paragraph 16 of plaintiffs' Complaint.

17. The Answering Defendants deny the allegations in paragraph 17 of plaintiffs' Complaint.

BACKGROUND BEXTRA

18. The Answering Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. The Answering Defendants further admit that Pfizer has marketed Bextra® as a prescription drug for the indications set forth in the approved package insert and as permitted by law. The Answering Defendants further admit that, during certain periods of time, Bextra® was manufactured for Searle and the during certain periods of time, Searle marketed and distributed Bextra®. The Answering Defendants further admit that, during certain periods of time, Pharmacia marketed Bextra®. The Answering Defendants deny all remaining allegations in paragraph 18 of plaintiffs' Complaint.

19. The Answering Defendants admit that plaintiff brought this civil action seeking monetary damages, but deny that plaintiff is entitled to any relief or damages. The Answering Defendants deny the remaining allegations of paragraph 19 of plaintiffs' Complaint.

20. The Answering Defendants deny the allegations in paragraph 20 of plaintiffs' Complaint.

21. The Answering Defendants admit that Pfizer has marketed Bextra® as a prescription drug for the indications set forth in the approved package insert and as permitted by law. The Answering Defendants further admit that, during certain periods of time, Bextra® was

manufactured for Searle and the during certain periods of time, Searle marketed and distributed Bextra®. The Answering Defendants further admit that, during certain periods of time, Pharmacia marketed Bextra®. The Answering Defendants deny all remaining allegations in paragraph 21 of plaintiffs' Complaint.

COUNT IX [sic]

22. The Answering Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

23. The Answering Defendants admit that Pfizer has marketed Bextra® as a prescription drug for the indications set forth in the approved package insert and as permitted by law. The Answering Defendants further admit that, during certain periods of time, Bextra® was manufactured for Searle and the during certain periods of time, Searle marketed and distributed Bextra®. The Answering Defendants further admit that, during certain periods of time, Pharmacia marketed Bextra®. The Answering Defendants deny all remaining allegations in paragraph 23 of plaintiffs' Complaint.

24. The Answering Defendants deny the allegations in paragraph 24 of plaintiffs' Complaint.

25. The Answering Defendants deny the allegations in paragraph 25 of plaintiffs' Complaint.

26. The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 26 of plaintiffs' Complaint regarding plaintiffs' alleged use of Bextra® and therefore deny the same. The Answering Defendants deny all remaining allegations in paragraph 26 of plaintiffs' Complaint.

27. The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 27 of plaintiffs'

Complaint regarding plaintiffs' alleged use of Bextra® and therefore deny the same. The Answering Defendants deny all remaining allegations in paragraph 27 of plaintiffs' Complaint.

28. The Answering Defendants deny the allegations in paragraph 28 of plaintiffs' Complaint.

29. The Answering Defendants deny the allegations in paragraph 29 of plaintiffs' Complaint.

COUNT X [sic]

30. The Answering Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

31. The Answering Defendants deny the allegations in paragraph 31 of plaintiffs' Complaint.

32. The Answering Defendants deny the allegations in paragraph 32 of plaintiffs' Complaint.

33. The Answering Defendants deny the allegations in paragraph 33 of plaintiffs' Complaint.

34. The Answering Defendants deny the allegations in paragraph 34 of plaintiffs' Complaint.

35. The Answering Defendants deny the allegations in paragraph 35 of plaintiffs' Complaint.

36. The Answering Defendants deny the allegations in paragraph 36 of plaintiffs' Complaint.

37. The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 37 of plaintiffs'

Complaint regarding plaintiffs' alleged use of Bextra® and therefore deny the same. The Answering Defendants deny all remaining allegations in paragraph 37 of plaintiffs' Complaint.

38. The Answering Defendants deny the allegations in paragraph 38 of plaintiffs' Complaint.

39. The Answering Defendants deny the allegations in paragraph 39 of plaintiffs' Complaint.

COUNT XI [sic]

40. The Answering Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

41. The Answering Defendants admit that Pfizer has marketed Bextra® as a prescription drug for the indications set forth in the approved package insert and as permitted by law. The Answering Defendants further admit that, during certain periods of time, Bextra® was manufactured for Searle and the during certain periods of time, Searle marketed and distributed Bextra®. The Answering Defendants further admit that, during certain periods of time, Pharmacia marketed Bextra®. The Answering Defendants deny all remaining allegations in paragraph 41 of plaintiffs' Complaint.

42. The Answering Defendants deny the allegations in paragraph 42 of plaintiffs' Complaint.

43. The Answering Defendants deny the allegations in paragraph 43 of plaintiffs' Complaint.

44. The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 44 of plaintiffs' Complaint regarding plaintiffs' alleged use of Bextra® and therefore deny the same. The Answering Defendants deny the remaining allegations in paragraph 44 of plaintiffs' Complaint.

45. The Answering Defendants deny the allegations in paragraph 45 of plaintiffs' Complaint.

46. The Answering Defendants deny the allegations in paragraph 46 of plaintiffs' Complaint.

47. The Answering Defendants deny the allegations in paragraph 47 of plaintiffs' Complaint.

COUNT XII [sic]

48. The Answering Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

49. The Answering Defendants state that paragraph 49 of plaintiffs' Complaint contains legal conclusions, to which no response is required. To the extent a response is required, the Answering Defendants admit that they had duties as are imposed by law. The Answering Defendants deny all remaining allegations in paragraph 49 of plaintiffs' Complaint.

50. The Answering Defendants deny the allegations in paragraph 50 of plaintiffs' Complaint, including all sub-parts.

51. The Answering Defendants deny the allegations in paragraph 51 of plaintiffs' Complaint.

52. The Answering Defendants deny the allegations in paragraph 52 of plaintiffs' Complaint.

COUNT XIII [sic]

53. The Answering Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

54. The Answering Defendants deny the allegations in paragraph 54 of plaintiffs' Complaint.

55. The Answering Defendants deny the allegations in paragraph 55 of plaintiffs' Complaint.

56. The Answering Defendants deny the allegations in paragraph 56 of plaintiffs' Complaint.

57. The Answering Defendants deny the allegations in paragraph 57 of plaintiffs' Complaint.

58. The Answering Defendants state that paragraph 58 of plaintiffs' Complaint contains legal conclusions to which no response is required. To the extent a response is required, the Answering Defendants admit that they had duties as are imposed by law. The Answering Defendants deny all remaining allegations in paragraph 58 of plaintiffs' Complaint.

59. The Answering Defendants deny the allegations in paragraph 59 of plaintiffs' Complaint.

60. The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 60 of plaintiffs' Complaint and therefore deny the same.

61. The Answering Defendants deny the allegations in paragraph 61 of plaintiffs' Complaint.

62. The Answering Defendants deny the allegations in paragraph 62 of plaintiffs' Complaint.

63. The Answering Defendants deny the allegations in paragraph 63 of plaintiffs' Complaint.

64. The Answering Defendants deny the allegations in paragraph 64 of plaintiffs' Complaint.

65. The Answering Defendants deny the allegations in paragraph 65 of plaintiffs' Complaint.

COUNT XIV [sic]

66. The Answering Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

67. The Answering Defendants deny the allegations in paragraph 67 of plaintiffs' Complaint.

68. The Answering Defendants deny the allegations in paragraph 68 of plaintiffs' Complaint.

69. The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 69 of plaintiffs' Complaint regarding plaintiff and/or his physician and therefore deny the same. The Answering Defendants deny all remaining allegations in paragraph 69 of plaintiffs' Complaint.

70. The Answering Defendants deny the allegations in paragraph 70 of plaintiffs' Complaint.

71. The Answering Defendants deny the allegations in paragraph 71 of plaintiffs' Complaint.

COUNT XV [sic]

72. The Answering Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

73. The Answering Defendants state the allegations in paragraph 73 of plaintiffs' Complaint state legal conclusions to which no response is required. To the extent a response is required, the Answering Defendants deny the allegations in paragraph 73 of plaintiffs' Complaint.

74. The Answering Defendants deny the allegations in paragraph 74 of plaintiffs' Complaint.

75. The Answering Defendants deny the allegations in paragraph 75 of plaintiffs' Complaint.

76. The Answering Defendants deny the allegations in paragraph 76 of plaintiffs' Complaint.

77. The Answering Defendants deny the allegations in paragraph 77 of plaintiffs' Complaint.

COUNT XVI [sic]

78. The Answering Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

79. The Answering Defendants state that the allegations in paragraph 79 of plaintiffs' Complaint state legal conclusions to which no response is required. To the extent a response is required, the Answering Defendants deny the allegations in paragraph 79 of plaintiffs' Complaint, including all sub-parts.

80. The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 80 of plaintiffs' Complaint regarding plaintiffs' alleged use of Bextra® and therefore deny same. The Answering Defendants deny all remaining allegations in paragraph 80 of plaintiffs' Complaint.

81. The Answering Defendants deny the allegations in paragraph 81 of plaintiffs' Complaint.

82. The Answering Defendants deny the allegations in paragraph 82 of plaintiffs' Complaint.

83. The Answering Defendants deny the allegations in paragraph 83 of plaintiffs' Complaint.

COUNT XVII [sic]

84. The Answering Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

85. The Answering Defendants deny the allegations in paragraph 85 of plaintiffs' Complaint.

86. The Answering Defendants deny the allegations in paragraph 86 of plaintiffs' Complaint.

87. The Answering Defendants deny the allegations in paragraph 87 of plaintiffs' Complaint.

88. The Answering Defendants deny the allegations in paragraph 88 of plaintiffs' Complaint, including its subparts.

89. The Answering Defendants deny the allegations in paragraph 89 of plaintiffs' Complaint.

90. The Answering Defendants deny the allegations in paragraph 90 of plaintiffs' Complaint.

91. The Answering Defendants deny the allegations in paragraph 91 of plaintiffs' Complaint.

92. The Answering Defendants deny the allegations in paragraph 92 of plaintiffs' Complaint.

The Answering Defendants admit that plaintiffs seek the relief requested in the "WHEREFORE" paragraph following paragraph 92, but specifically deny that plaintiffs are entitled to any relief.

WHEREFORE, the Answering Defendants request that plaintiffs' Complaint, and all claims alleged therein, be dismissed with prejudice, that the Answering Defendants be awarded the costs, disbursements and attorneys' fees incurred in the defense of this action, and that the Answering Defendants be granted any other relief to which they may be entitled.

GENERAL DENIAL

The Answering Defendants deny all allegations and/or legal conclusions set forth in plaintiffs' Complaint that have not been previously admitted, denied, or explained.

PREAMBLE TO AFFIRMATIVE DEFENSES

The Answering Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial.

AFFIRMATIVE AND OTHER DEFENSES

1. The Complaint fails to state a claim upon which relief can be granted.
2. This action is barred, in whole or in part, because the FDA has exclusive or primary jurisdiction over the matters asserted in plaintiffs' Complaint.
3. The claims asserted in plaintiffs' Complaint are preempted, in whole or in part, by federal law under the Supremacy Clause of the United States Constitution.
4. The claims asserted in plaintiffs' Complaint are barred, in whole or in part, because plaintiffs lack standing and/or capacity to bring such claims.
5. The claims asserted in plaintiffs' Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of the Answering Defendants' conduct.
6. Because Bextra® is a prescription drug, the claims asserted in plaintiffs' Complaint are barred, in whole or in part, by the learned intermediary doctrine.

7. The claims asserted in plaintiffs' Complaint are barred, in whole or in part, because the product was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was marketed with adequate and sufficient warnings.

8. The claims asserted in plaintiffs' Complaint are barred, in whole or in part, by the economic loss doctrine.

9. The claims asserted in plaintiffs' Complaint are barred, in whole or in part, because plaintiffs have suffered no injury.

10. The claims asserted in plaintiffs' Complaint are barred, in whole or in part, by the applicable statute(s) of limitations and/or repose.

11. The claims asserted in plaintiffs' Complaint are barred, in whole or in part, by plaintiffs' failure to mitigate damages.

12. The claims asserted in plaintiffs' Complaint are barred because the utility of Bextra® outweighs the alleged risks.

13. The claims asserted in plaintiffs' Complaint are barred because Bextra® was designed, tested, manufactured, and labeled in accordance with state-of-the-art and industry standards existing at the time of sale.

14. The claims asserted in plaintiffs' Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

15. The claims asserted in plaintiffs' Complaint are barred because plaintiffs lack privity with the Defendant.

16. The methods, standards, and techniques utilized with respect to the manufacture, testing, design, and marketing of Bextra®, if any, used in this case, including adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was designed, tested, manufactured, and marketed.

17. The claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the product was not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

18. The claims asserted in plaintiffs' Complaint are barred, in whole or in part, by the doctrines of laches, waiver, and/or estoppel.

19. The claims must be dismissed because plaintiffs would have taken the product even if the product labeling contained the information that plaintiffs contend should have been provided.

20. The Answering Defendants state that the prescription drug Bextra® complied with the then-applicable product safety regulations promulgated by the FDA. Compliance with such regulations demonstrates that the Defendant exercised due care in the provision of this prescription drug, and that it was neither defective nor unreasonably dangerous.

21. The claims asserted in plaintiffs' Complaint are barred, in whole or in part, because plaintiffs have not suffered an injury or a significantly increased risk of contracting a serious latent disease or injury as a result of Bextra® use.

22. The claims asserted in plaintiffs' Complaint are barred, in whole or in part, because plaintiffs lack an adequate scientific basis to demonstrate any resulting harm or increased risk of future harm as a result of Bextra® use.

23. To the extent the claims asserted in plaintiffs' Complaint are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution and analogous provisions of the applicable state's constitution.

24. Losses, if any, to plaintiffs are subject to an offset for benefits received by plaintiff resulting from any alleged use of Bextra®.

25. If plaintiffs sustained any damages as alleged, said damages were directly and proximately caused by the negligence or fault of the parties other than the Answering Defendants, whether named or unnamed in plaintiffs' Complaint, over whom the Answering Defendants had no supervision or control and for whose actions and omissions the Answering Defendants has no legal responsibility. Plaintiffs' recovery, if any, should therefore be apportioned in accordance with the applicable law.

26. The damages claimed by plaintiffs, if any, resulted from an intervening or superseding cause and/or causes, and any act or omission on the part of the Answering Defendants was not the proximate and/or competent producing cause of such alleged damages.

27. If plaintiffs sustained any damages as alleged, such damages arose from, and were caused by, risks, hazards and dangers knowingly assumed by plaintiffs. Plaintiffs' recovery accordingly is barred or should be reduced by plaintiffs' assumption of the risk.

28. Plaintiffs' claims are barred, in whole or in part, by the doctrine of accord and satisfaction.

29. The Answering Defendants are entitled to credit for any settlement of claims for alleged injuries and damages made by plaintiffs with any other defendant or other person or entity.

30. Plaintiffs' fraud-based claims, if any, are not stated with particularity as required by Rule 9 of the Federal Rules of Civil Procedure.

31. The claims asserted in plaintiffs' Complaint are barred as a matter of law pursuant to Restatement (Second) of Torts § 402A, comments j & k.

32. This Court should abstain from adjudicating plaintiffs' claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the FDA.

33. Plaintiffs' claims are preempted by federal law and regulations, including but not limited to the Federal Food, Drug & Cosmetic Act, 21 U.S.C. §301 *et. seq.*, the regulations promulgated thereunder, and the United States Constitution, Article IV, clause 2.

34. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention, in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

35. The claims asserted in plaintiffs' Complaint are barred, in whole or in part, by the doctrines of primary jurisdiction and exhaustion of administrative remedies, because the FDA has exclusive or primary jurisdiction over the matters asserted in plaintiffs' Complaint.

36. The claims asserted in plaintiffs' Complaint are barred, in whole or in part, because the product is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated thereunder, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by

FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying the product. Accordingly, plaintiffs' claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

37. The claims asserted in plaintiffs' Complaint are barred as a matter of law pursuant to Restatement (Third) of Torts: Product Liability § 4, *et seq.*, because Bextra® complied with applicable product safety statutes and administrative regulations.

38. The claims asserted in plaintiffs' Complaint are barred as a matter of law pursuant to Restatement (Third) of Torts: Product Liability §§ 6(c) and 6(d) as reasonable physicians knowing of the reasonably foreseeable risks and therapeutic benefits associated with Bextra® would have prescribed and did prescribe Bextra® for plaintiffs and the Answering Defendants provided reasonable instructions and/or warnings to prescribing physicians.

39. Plaintiffs' claims are barred in whole or in part because the product "provides net benefits for a class of patients" within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

40. Plaintiffs' alleged injuries and damages, if any, were caused by the acts or omissions of plaintiffs, and/or by the fault of them as specified in Mo. Rev. Stat. § 537.765, and thus any recovery might be reduced accordingly or eliminated altogether.

41. Plaintiffs' claims are barred by the limitations and defenses set out in the Missouri Product Liability Act, Mo. Rev. Stat. § 537.760 *et seq.*, including but not limited to, the "state of the art" defenses as defined in Mo. Rev. Stat. § 537.764. Defendants incorporate by

reference all defenses and/or limitations set forth or referenced in the Missouri Product Liability Act.

42. The Complaint fails to state facts sufficient to sustain a claim for, or recovery of, punitive damages, and any award of punitive damages in this case would violated the due process clause of the Fourteenth Amendment to the United States Constitution and similar provisions of the Constitution, law, and public policy of Missouri.

43. The Answering Defendants deny that they are liable for any damages in this case. The Answering Defendants contend, however, that any damage award to plaintiffs that utilizes the Missouri joint and several liability scheme would be unconstitutional, as this scheme is violative of the Answering Defendants' due process and equal protection guarantees under the United States and Missouri Constitutions. The Missouri joint and several liability scheme, under Mo. Rev. Stat. § 537.067, violates the Answering Defendants' due process guarantees because no legitimate state interest supports § 537.067, and, furthermore, no rational relationship exists between a legitimate state interest and the promotion of the Missouri joint and several liability scheme. Additionally, the Missouri system of assessing joint and several liability violates the Answering Defendants' equal protection guarantees because it operates to create arbitrary classifications of individuals, and to treat similarly situated individuals dissimilarly under the law. The joint and several liability scheme is also unconstitutionally void for vagueness under the United States and Missouri Constitutions. Thus, the scheme is unconstitutional and should not be applied in this action.

44. The imposition of punitive damages violates the Due Process and Equal Protection provisions of U.S. Const. Amend. XIV; to wit, these Defendants have not been given fair notice of the standard of conduct which could subject them to a claim for punitive damages,

and have not been given fair notice of the amount of punitive damages that may accompany a finding of liability.

45. Plaintiffs' claims for punitive damages violate these Defendants' rights under the Fifth, Sixth, Seventh, Eighth, and Fourteenth Amendment of the Constitution of the United States of America.

46. Plaintiffs' claims for punitive damages are limited or barred by the standards governing exemplary damages awards which arise under the United States Constitution and decisions of the United States Supreme Court including, but not limited to: *BMW of North America v. Gore*, 116 U.S. 1589 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); and *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

WHEREFORE, the Answering Defendants request that plaintiffs' Complaint, and all claims alleged therein, be dismissed with prejudice, that the Answering Defendants be awarded the costs, disbursements and attorneys' fees incurred in the defense of this action, and that the Answering Defendants be granted any other relief to which they may be entitled.

JURY DEMAND

The Answering Defendants demand a trial by jury as to all issues so triable.

Respectfully submitted,

SHOOK, HARDY & BACON, L.L.P.

/s/ Jon A. Strongman

Harvey L. Kaplan, E.D. Bar #18126
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Jon A. Strongman, E.D. Bar #118013

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**ATTORNEYS FOR DEFENDANTS
PFIZER INC., PHARMACIA CORPORATION,
AND G.D. SEARLE LLC**

CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of April, 2007, a true and correct copy of the foregoing document was served by via the Court's electronic notification system and U.S. Mail upon:

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/s/ Jon A. Strongman
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Corporation and G.D. Searle LLC